



DEPARTMENT OF HEALTH & HUMAN SERVICES

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John E. Kanner, C.O. 9-3-97
Public Health Service

CERTIFIED
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

September 3, 1997

WARNING LETTER
97-DT-16

Mr. Sam Sanghavi, President
Indian Groceries & Spices
7300 N. St. Louis Avenue
Skokie, IL 60076

Entry No.: 112-2141643-9
Product: Chana Dal

Dear Mr. Sanghavi:

An inspection was made of your food processing operations on July 24 & 28, 1997 by Investigator Mark Kaspar of our Chicago District Office. The inspection found that the referenced entry, consisting of [REDACTED]/50 Kg. bags of Chana Dal (chick peas), that was detained by our office on June 23, 1997, was processed into flour and distributed into commerce without a release from the Food and Drug Administration (FDA). Our inspection found that none of the bulk imported product from this entry was available at your firm and you had no processing records which showed that the chick peas from this specific entry were processed into flour by your firm.

This is a violation of Title 21, Code of Federal Regulations, Part 1.90 (21 CFR 1.90), which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. The U.S. Customs Service issued a Notice of Refusal of Admission and Notice of Redelivery (copy enclosed) on August 19, 1997 for the above referenced entry.

Failure to prevent future distribution of entries prior to receipt of a May Proceed or Release Notice may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination of future entries. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

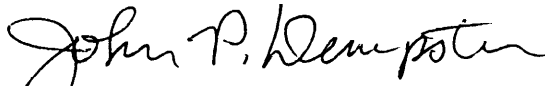
We acknowledge receipt of your letter dated August 2, 1997 regarding the circumstances surrounding the processing and distribution of the Chana Dal from the referenced entry. While your letter provides a chronology of events surrounding the distribution of this product, it does not provide the specific steps you have taken to prevent this from occurring again.

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Please notify us in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct this violation and to prevent its recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be made.

Your response should be directed to this office to the attention of Mr. John E. Klemmer, Compliance Officer.

Sincerely yours,


Raymond V. Mlecko
for Acting District Director
Detroit District